



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

M✓

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/282,239

03/31/99

GOLDMAN

S

19603/1426

HM12/0828

MICHAEL L GOLDMAN ESQ
NIXON HARGRAVE DEVANS & DOYLE LLP
CLINTON SQUARE PO BOX 1051
ROCHESTER NY 14603

EXAMINER

HUTSON, R

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

08/28/01

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/282,239

Applicant(s)

GOLDMAN ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants amendment of claims 17-20 is acknowledged. Claims 1-20 are still at issue and are present for examination.

Applicants' arguments filed on 6/11/2001, paper No. 12, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 1-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The rejection of claims 17-20 under 35 U.S.C. 102(a) as being anticipated by Wang et al. (Annals of Neurology, 44:438, September, 1998) has been withdrawn on the basis of applicants filing of a 1.132 declaration which states that the Wang et al. reference is not by another.

Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Armstrong et al. (Journal of Neuroscience 12 (4): 1538-1547, April 1992).

This rejection is stated in the previous office action.

Applicants traverse this rejection on the basis that the pre-oligodendrocytes of Armstrong and the oligodendrocytes they produce did not undergo cell division (i.e. mitosis) when treated with mitosis-triggering agents, and thus it is clear that these cells are not mitotic, as was recognized by Armstrong et al. This is in contrast to the oligodendrocyte progenitor cells of the present invention. Thus since Armstrong et al. does not teach mitotic oligodendrocyte progenitor cells it cannot be used as a proper basis to reject the claims. Applicants argument is persuasive with respect to claims 19 and 20, although applicant is reminded that claims 17 and 18 are not drawn to mitotic oligodendrocyte progenitor cells, but rather oligodendrocytes **generated from** mitotic progenitor cells. For this reason, applicants argument traversing the rejection of claims 17 and 18 is not found persuasive, since clearly the enriched or purified oligodendrocytes of Armstrong et al. were generated from mitotic progenitor cells.

Claims 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirschenbaum et al. (Cerebral Cortex 6: 576-589, Nov/Dec 1994).

This rejection is stated in the previous office action.

Applicants traverse this rejection on the basis that Kirschenbaum et al. does not disclose mitotic oligodendrocyte progenitor cells or oligodendrocytes generated from such cells, thus the rejection should be withdrawn. As discussed above applicant is reminded that claims 17 and 18 are not drawn to mitotic oligodendrocyte progenitor cells, but rather oligodendrocytes **generated from** mitotic progenitor cells and it is

Art Unit: 1652

believed those the oligodendrocytes taught by Kirschenbaum et al. are generated from mitotic oligodendrocyte progenitor cells.

With respect to claims 19 and 20 applicants statement that Kirschenbaum et al. does not disclose mitotic oligodendrocyte progenitor cells or oligodendrocytes generated from such cells is without evidence. It appears that such a statement should be supported by a 1.132 declaration. Irrespective it is believed that the oligodendrocytes taught by Kirshenbaum et al. were generated from mitotic oligodendrocyte progenitor cells since all cells must have been generated from a mitotic cell. Further, Kirshenbaum et al. state in there abstract "while O4+ oligodendrocytes, although the predominant cell type, were largely post mitotic". Thus it appears that while the oligodendrocytes were largely post mitotic, some albeit a small number were mitotic.

Claims 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bottenstein (U.S. Patent No: 5,276,145, January 1994).

Bottenstein teach compositions comprising a purified preparation of neural progenitor regulatory factor and methods of its use. Bottenstein specifically teach the preparation and characterization of neonatal rat brain cultures (Table I, columns 12-16). Bottenstein specifically teach additional morphological and antigenic characterization of there cultures (Column 23, lines 47-68). After 4 days in vitro cultures treated with 33% B104 conditioned medium contain abundant numbers of small A2B5-positive, bipolar glial progenitor cells which appear to be highly mitotic. These cells give rise to oligodendrocytes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bottenstein (U.S. Patent No: 5,276,145, January 1994).

As discussed above, Bottenstein teach compositions comprising a purified preparation of neural progenitor regulatory factor and methods of its use in culturing rat brain A2B5-positive, bipolar mitotic glial progenitor cells.

One of ordinary skill in the art would be motivated to use the composition and methods of isolating and culturing rat mitotic glial progenitor cells to isolate and culture human mitotic glial progenitor cells for their use in the development of a rational therapeutic regime for treatment of demyelinating disorders such as multiple sclerosis or treatment of traumatic injury to the CNS. The reasonable expectation of success of achieving an enriched or purified preparation of glial progenitor cells (oligodendrocyte progenitor cells) comes from the results of Bottenstein and the similarity of the different cell types between rat and human brains.

Thus claims 18 and 20 are made obvious by Bottenstein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/282,239
Art Unit: 1652

Page 7

Richard Hutson, Ph.D.
August 24, 2001


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1300
1600